UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

SHREVEPORT DIVISION

JAMES P. MCQUISTON, ET AL.

versus

CIVIL ACTION NO. 07-1723
JUDGE TOM STAGG

BOSTON SCIENTIFIC CORPORATION
and ABC INSURANCE COMPANY

MEMORANDUM RULING

Before the court is a motion for summary judgment filed by the defendant, Boston Scientific Corporation ("Boston Scientific"). See Record Document 27. For the reasons set forth below, Boston Scientific's motion is **GRANTED.**

I. BACKGROUND

A. Facts.

On September 1, 2006, Dr. Thomas Brown performed a percutaneous transluminal coronary angioplasty and stent procedure on the plaintiff, James P. McQuiston. Mr. McQuiston had been to his cardiologist on August 29, 2006, with a history of coronary artery disease, including prior coronary artery bypass graft surgery in 1989 and 1997, a history of congestive heart failure, valvular heart disease, hypertension, hypothyroidism, and a history of having suffered a previous

myocardial infarction and a previous transient ischemic attack. Mr. McQuiston's physician scheduled him for a heart catheterization procedure on September 1, and he had a TAXUS Express Paclitaxel-Eluting Coronary Stent System ("TAXUS Stent") implanted in his coronary artery. Mr. McQuiston was discharged from the hospital the next day. See Record Document 27, Exs. M and N. He alleges that he "experienced significant deterioration during the treatment period post-stent placement." Record Document 10 at 2.

Boston Scientific designed, manufactured and sold the TAXUS Stent. Mr. McQuiston and his wife (hereinafter collectively referred to as "McQuiston") filed suit in state court against Boston Scientific, alleging that the TAXUS Stent "malfunctioned and failed to deflate, causing permanent and serious injuries" to him. Record Document 1, Petition at 1. McQuiston contends that the TAXUS Stent was negligently designed, manufactured, marketed, sold, tested and distributed. See id. McQuiston further asserts claims for breach of warranty, failure to warn and fraud. See id. Boston Scientific removed the case to this court on the basis of diversity jurisdiction and filed the instant motion for summary judgment, arguing that McQuiston's claims are preempted. See Record Document 27.

B. History Of The Taxus Stent And The Medical Device Amendments.

Congress passed the Medical Device Amendments ("MDA") to the Food,

Drug and Cosmetics Act in 1976. The MDA places each medical device into one of three classes depending on the degree of risk the device poses to the public. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S. Ct. 2240, 2246 (1996) (citing 21 U.S.C. §§ 360c-360k) ("Lohr"). Devices are classified as Class I and subject only to minimal regulation by "general controls" if they present no unreasonable risk of illness or injury. See Lohr, 518 U.S. at 476-77, 116 S. Ct. at 2246. Class II devices are potentially more harmful than Class I and, although they can be marketed without prior approval, manufacturers of such devices must comply with federal performance regulations known as "special controls." See id. at 477, 116 S. Ct. at 2246. Class III is reserved for devices that "either presen[t] a potential unreasonable risk of illness or injury, or which are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." Id. (internal marks omitted). The manufacturer of a new Class III device must provide the Food and Drug Administration ("FDA") with a "reasonable assurance" that the device is both safe and effective through the rigorous premarket approval process ("PMA") before the device may be introduced to the market. See id. The TAXUS Stent is a Class

III medical device.[1]

The Food and Drug Administration granted Boston Scientific's premarket approval application for the TAXUS Stent on March 4, 2004. According to the FDA's "Premarket Approval (PMA) Database," to date Boston Scientific has submitted, and the FDA has approved, a least forty-five supplements to the TAXUS Stent premarket approval application since granting approval on March 4, 2004. These include FDA approval of three updates to the TAXUS Stent Directions for Use.

The information on which the FDA made the determination of premarket

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[1]McQuiston attempts to argue otherwise in her opposition, contending that the TAXUS Stent contains a "pharmaceutical component." Boston Scientific counters that McQuiston has, in a previously filed motion to compel, admitted that the TAXUS Stent is a Class III device. See Record Document 37 at 8. Boston Scientific, however, notably fails to mention that McQuiston asserts that "the stent also has a pharmaceutical component" in the very next sentence of the same document. Id. However, the court notes that in McQuiston's opposition to Boston Scientific's motion for summary judgment, McQuiston specifically states: "Defendants are right in identifying the Taxus Stent as a Class III medical device." Record Document 47 at 5. Regardless, it is clear to the court that the TAXUS Stent is a Class III device under the MDA and that the presence of a pharmaceutical component does not prevent it from being such. The Secretary of Health and Human Services had the duty of determining the "primary mode of action" of a combination product pursuant to 21 U.S.C. § 353(g) (2002). In May of 2001, following a request for designation from Boston Scientific pursuant to 21 C.F.R. § 3, the FDA determined that "the paclitaxel- eluting stent primarily fulfills a device function" and would be subject "to premarket review and approval under the medical device provisions" of the Federal Food, Drug and Cosmetic Act. See Record Document 55, Ex. A.

approval for the TAXUS Stent came from Boston Scientific or was based on information provided by Boston Scientific. The premarket approval application and its amendments contained over 40,000 pages. The information included results of clinical studies, non-clinical studies and additional information all generated by and/or based on information provided by Boston Scientific.

II. ANALYSIS

A. Summary Judgment Standard.

Summary judgment is proper pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986). "Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 263 (5th Cir. 2002). If the movant demonstrates the absence of a genuine issue of material fact, "the nonmovant must go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial." Gen.

Universal Sys., Inc. v. Lee, 379 F.3d 131, 141 (5th Cir. 2004) (citations and quotations omitted). Where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant, then summary judgment should be granted. See Boudreaux v. Swift Transp. Co., 402 F.3d 536, 540 (5th Cir. 2005).

B. Preemption Analysis.

Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Lohr, 518 U.S. at 474, 116 S. Ct. at 2245 (citing the preamble to the MDA of 1976, 90 Stat. 539). Prior to the enactment of the MDA, regulation of medical devices was largely left to the states. However, the MDA enacted a regime of detailed federal oversight of medical devices. See Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999, 1003 (2008). The MDA's preemption provision, 21 U.S.C. § 360k(a), governs the extent to which the MDA preempts state law. It reads:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of a device or to any other matter included in a requirement

> applicable to the device under this chapter.

Id.

The FDA has promulgated regulations interpreting section 360k, which state:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

21 C.F.R. § 808.1(d).

Class III devices, like the TAXUS Stent at issue in this case, are subject to the highest level of federal oversight. See Riegel, 128 S. Ct. at 1003. The premarket approval process for new Class III devices first requires the manufacturer to submit a multivolume application. This information must include the results of a good faith investigation and studies of the device's safety and effectiveness. The process also includes a review of the device's proposed labeling and instructions. The FDA determines whether the proposed labeling is false or misleading. The Supreme Court has described the premarket approval process for Class III devices as "rigorous." Id. at 1004 (citing Lohr, 518 U.S. at 477, 116 S. Ct. 2240). Premarket approval is only granted if the FDA finds that there is a "reasonable assurance" of the subject device's "safety and effectiveness." Id. (quoting 21 U.S.C. § 360e(d)).

The FDA is granted discretion to "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Id. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 1005.

Boston Scientific claims that every detail of its TAXUS Stent and its packaging have been approved by the FDA. Therefore, Boston Scientific argues, state law claims alleging that these specifications are inadequate would conflict with the FDA's determination and are preempted by federal law.

C. The Supreme Court's Decision In Riegel.

In Riegel v. Medtronic, decided in 2008, the Supreme Court set forth a two-prong analysis for determining whether a plaintiff's state law claims are preempted by the MDA. First, it must be determined that the federal government has established requirements that are applicable to the device. See Riegel, 128 S. Ct. at 1006. If there are federal requirements for the device, then a court must next determine whether the plaintiff's state law claim is based on a state requirement with respect to the device that is "different from or in addition to" the federal requirements, and that relates to the safety and effectiveness of the device. Id.

(citing 21 U.S.C. § 360k(a)). If the state requirement is different from or in addition to the federal requirements, then such a state requirement is preempted by the MDA.

In Riegel, the plaintiff filed suit after a catheter used in his medical procedure ruptured. See id. at 1005-06. The plaintiff's suit alleged that the device was designed, labeled and manufactured in a manner inconsistent with New York state law. The Supreme Court affirmed the circuit court and district court's dismissal of the action based on MDA preemption. See id. The catheter device at issue was a Class III device that had undergone the FDA's premarket approval process.

In addressing the first prong of the preemption analysis, the Riegel Court reasoned that the premarket approval process "imposes 'requirements' under the MDA." Id. at 1007. The premarket approval is specific to the individual device. The premarket approval process does not constitute an exemption from federal safety review but instead, the process *is* the federal safety review. See id. The premarket approval process itself establishes federal requirements for a device, so any device that has been approved by that process will satisfy the first prong of the preemption analysis. See id. The Supreme Court then went on to discuss the second prong of the preemption analysis. In the Riegel case, the plaintiff had based his claims on state common-law duties. The Court equated state common-law duties with state "requirements" and determined that "[a]bsent other indication,

reference to a State's 'requirements' includes its common-law duties." Id. at 1008. Such state "requirements" were preempted when applied to a specific medical device that has undergone premarket approval. Id. at 1007-08. Additionally, the Court reaffirmed its holding in Lohr, 518 U.S. at 512,[2] that common-law causes of action for negligence and strict liability imposed state "requirements" and were preempted when applied to a specific medical device. Id. at 1007. In his opinion for the court, Justice Scalia confirmed that removal of all judicial recourse "is exactly what a pre-emption clause for medical devices does by its terms." Id. at 1009. The Court's analysis, along with Justice Scalia's statement, indicates the

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[2]In Lohr, the plaintiff claimed she was injured when her pacemaker failed. See Lohr, 518 U.S. at 480-481, 116 S. Ct. at 2248. She and her husband brought claims against Medtronic. In a plurality decision, the Supreme Court analyzed whether the claims, brought under Florida state law, were preempted by the MDA's section 360k preemption provision. See id. at 481-482, 116 S. Ct. at 2248-49. After extensive analysis, the Court found that none of the Lohrs' claims based on allegedly defective manufacturing or labeling were preempted. See id. at 502, 116 S. Ct. at 2259. The Court emphasized the fact that the pacemaker at issue was approved after the manufacturer submitted a premarket notification, a process also known as a section 510(k) process. See id. at 478, 116 S. Ct. at 2247. Through this process, if the FDA concludes on the basis of the premarket notification that the device is substantially equivalent to a pre-existing device, the device can be marketed without further regulatory analysis. See id. The Court stated that the section 510(k) process, which typically takes about twenty hours to complete, is by no means comparable to the PMA process, which requires 1,200 hours. See id. at 478-479, 116 S. Ct. at 2247.

breadth of MDA preemption post-Riegel.[3]

D. Preemption Analysis Of McQuiston's Claims.

As previously stated, the TAXUS Stent is a Class III device under the MDA. Thus, the TAXUS Stent was subject to the highest scrutiny under the MDA by virtue of its approval through the "rigorous" premarket approval process set forth for Class III devices. See Riegel, 128 S. Ct. at 1004 (citing Lohr, 518 U.S. at 477,

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[3]In Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919 (5th. Cir. 2006), a case decided by the Fifth Circuit prior to Riegel, the Fifth Circuit stated that this circuit uses the Martin/Lohr test to analyze products liability claims against PMA-approved devices. See id. at 928-30 (citing Martin v. Medtronic, Inc., 254 F.3d 573 (5th Cir. 2001) and Lohr, 518 U.S. 470, 116 S. Ct. 2240). The test requires a court to analyze the claims and determine whether the duties enforced by such claims would threaten the federal duties imposed by the PMA process. See id. at 930. The Gomez court found that the plaintiff's claims for negligent design and defective design were preempted because the FDA studied and approved the device's design through the PMA process. See id. The FDA also approved the labeling, warnings, instructions, and training process for the device during the PMA process; therefore, any claims of inadequacy in any of these areas were also preempted. See id. at 931.

The plaintiff in Gomez also argued that her warranty claims should not be preempted because after the completion of the PMA, the manufacturer acquired additional information about the risks associated with the product but did not provide updated warnings. See id. The court stated that because the manufacturer had an ongoing obligation to the FDA to report new information obtained after the approval of the device, any related state law claims would interfere with the federal scheme and were preempted. See id. at 931-32. The court also found that a claim for the breach of any express warranties provided under Louisiana law would also be preempted because the duties imposed by such claims were potentially inconsistent with the federal regulatory scheme. See id. at 932. The only claim that the court found was not preempted was a defective manufacturing claim alleging that the device did not comply with the FDA-approved specifications. See id.

116 S. Ct. at 2240). Boston Scientific argues that it is entitled to summary judgment because McQuiston's state law claims conflict with federal requirements imposed by the FDA and are, therefore, preempted. Boston Scientific asserts that since the TAXUS Stent is a Class III device, information must be continually provided to the FDA and all changes to the product must be approved. McQuiston argues, inter alia, that even if the TAXUS Stent is a Class III device, the facts he alleges encompass a claim that the TAXUS Stent does not comply with FDA requirements, which is not preempted.

Applying the two-prong Riegel preemption analysis to the present case, this court is compelled to conclude that McQuiston's claims are preempted. First, there can be no argument that the TAXUS Stent was subject to the premarket approval process and the federal government established requirements for the device through that process. The analysis then shifts to the second prong for a determination of whether McQuiston's claims are based on a state requirement with respect to the device that are "different from or in addition to" the federal requirements, and that relate to the safety and effectiveness of the device.

McQuiston does not appear to dispute the fact that many of his claims are preempted by Riegel. His arguments to the court focus instead on five general

areas, many of which are irrelevant to the current issues.[4] Ultimately, however, McQuiston does not challenge the fact that Riegel mandates preemption of many of his claims. Regardless, the court will proceed to analyze each of McQuiston's claims seriatim.

1. Design Defect.

McQuiston contends that the TAXUS Stent was "in a defective and unreasonably dangerous condition as designed, taking into account the utility of the product and the risk involved in its use." Record Document 1, Petition at 3. However, a finding under state law that the TAXUS Stent was improperly designed would impose a requirement that differs from the design that has been approved by the FDA. Because this state requirement would be "different from, or in addition to" the requirements imposed by federal law, this claim is expressly preempted.

2. Inadequate Testing.

McQuiston asserts that the TAXUS Stent was defective "due to inadequate testing." Id. This claim essentially challenges the safety testing that formed the basis upon which the FDA approved the TAXUS Stent PMA. A finding under state

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[4]For example, McQuiston suggests that future legislation will "nullify" Riegel. See Record Document 47 at 4. However, reliance upon prospective legislation in an attempt to avoid preemption under the current state of the law as set forth in Riegel is a futile, and ineffective, strategy by McQuiston.

law that the TAXUS Stent was inadequately tested would impose a requirement that differs from the testing that was approved by the FDA. Because this state requirement would be "different from, or in addition to" the requirements imposed by federal law, this claim is also expressly preempted.

3. Warnings Claims.

McQuiston alleges that the TAXUS Stent is defective because Boston Scientific marketed and continues to market the TAXUS Stent despite "opportunities for more meaningful and effective warnings." Record Document 1, Petition at 4. He further alleges that Boston Scientific "failed to provide adequate post-marketing warnings or instructions after the manufacturer knew of the risk of injury from the [TAXUS Stent] via post-marketing data." Id. at 3. Both claims are premised on the argument that Boston Scientific should have provided warnings different from, or in addition to, the warnings that were approved by the FDA. A finding under state law that the warnings provided with the TAXUS Stent were inadequate would impose requirements that differ from the warnings that were approved by the FDA. Because a state requirement would be "different from, or in addition to" the requirements imposed by federal law, these claims are expressly preempted.

4. Breach Of Express And Implied Warranties.

McQuiston contends that Boston Scientific "breached warranties." Record Document 1, Petition at 2. McQuiston does not clarify whether he is asserting a claim for breach of an express warranty or a claim for breach of an implied warranty. Regardless, either claim is preempted.

Although Riegel did not directly address a claim for breach of express warranty, in Gomez v. St. Jude Med. Diag Div., Inc., 442 F.3d 919 (5th Cir. 2006), the Fifth Circuit has considered and answered this question. The Gomez court concluded that when the representations at issue are approved by the FDA through the premarket approval process, "the duties arising under the Louisiana breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme." Id. at 932. As a result, any such claim is preempted. See id.

The Gomez court did not specifically decide the issue of Louisiana implied warranty claims. However, the FDA has thoroughly examined the manufacturing process, the safety, and the labeling of every PMA-approved product. See Martin, 254 F.3d at 584-85. A determination that even though the product complies with the FDA requirements, it has a problem causing it to breach an implied warranty, would impose requirements different from or in addition to those imposed by the FDA. See Riegel, 128 S. Ct. at 1009-1011. Accordingly, because the FDA

approved the TAXUS Stent's labeling and warnings, McQuiston's breach of express and implied warranties claims are preempted.

5. Manufacturing Defect.

McQuiston contends that Boston Scientific "failed to exercise ordinary care in the . . . manufacture[]" of the TAXUS Stent. Record Document 1, Petition at 3. The manufacturing process about which McQuiston complains is the process that was approved by the FDA by virtue of the PMA application, which includes "a full description of the methods used in, and the facilities and controls used for, the manufacture" of a medical device. Riegel, 128 S. Ct. at 1004 (quoting 21 U.S.C. § 360e(c)(1)). A finding under state law that the TAXUS Stent was negligently manufactured would impose a requirement that differs from the manufacturing requirements that were approved by the FDA. Because this state requirement would be "different from, or in addition to" the requirements imposed by federal law, this claim is expressly preempted.

6. Negligence And Fraud Under State Law.

The Louisiana Products Liability Law ("LPLA") provides "the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. 9:2800.52. The LPLA sets forth four exclusive theories of recovery against a manufacturer: (1) defect in construction or composition; (2) defect in design; (3)

inadequate warning; or (4) failure to comply with an express warranty. La. R.S. 9:2800.54(B)(1-4). Louisiana courts have "held the LPLA subsumes all possible causes of action, with the exception of a claim in redhibition." Touro Infirmary v. Sizeler Architects, 947 So.2d 740, 744 (La. App. 4 Cir. 2006). Federal courts applying Louisiana law have also employed this principle. See Bezet v. Smith & Wesson Corp., No. 08-685, 2008 WL 632080 (M.D. La. Mar. 11, 2009); Borskey v. Medtronics, No. 94-2302, 1998 WL 122602, *4 (E.D. La. Mar. 18, 1998). "While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer." Jefferson v. Lead Indus. Ass'n, Inc., 106 F.3d 1245 at 1251 (5th Cir.1997) (incorporating district court opinion dismissing plaintiff's claims, 930 F.Supp. 241 (E.D. La. May 31, 1996) (J. Vance)). The Jefferson court also affirmed the district court's dismissal of the plaintiff's claims for fraud by misrepresentation. See id. Accordingly, McQuiston's claims which are raised independent of the LPLA, including negligence and fraud,[5]

[5]McQuiston's claims are also preempted to the extent he is asserting fraud-on-the-FDA under state law with regard to Boston Scientific's alleged "[l]ying or withholding critical information." See Buckman Co. v. Pl.'s Legal Comm., 531 U.S. 341, 348, 121 S. Ct. 1012 (2001) (holding that "state law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law").

will be dismissed.

7. Noncompliance With FDA-Approved Specifications.

Boston Scientific argues that since McQuiston did not include in his complaint a claim that the TAXUS Stent used in his surgery did not comply with the FDA requirements, he cannot now do so. In response, McQuiston argues that his complaint encompassed such claims and that a specific statement of such claim is not required since the complaint was filed in a Louisiana state court which requires only fact pleading.

This court has repeatedly reviewed McQuiston's petition in search of a claim that Boston Scientific failed to comply with the FDA's requirements and has found none. McQuiston has been aware that Boston Scientific intended to assert preemption as a defense since at least March of 2008. Yet, in the ensuing time since March of 2008, McQuiston has not once sought to amend his complaint to assert claims that Boston Scientific failed to comply with FDA requirements. McQuiston, instead, chose to stand on the allegations in his petition--allegations that simply do not encompass a claim that Boston Scientific failed to comply with FDA requirements. McQuiston's last-minute attempts through pleadings to manufacture a claim that clearly was not alleged in his complaint and that would survive preemption will not suffice. Nor can this court conclude that McQuiston's

allegation that Boston Scientific "fail[ed] to exercise ordinary care" encompasses a failure to comply with FDA specifications. This court will not strain credulity and manufacture a claim on McQuiston's behalf. A claim asserting that Boston Scientific did not comply with FDA specifications simply does not exist in the petition.

8. Loss Of Consortium.

McQuiston's wife asserts a claim for loss of consortium. See Record Document 1, Petition at 4-5. Although Boston Scientific asserts that the Supreme Court in Riegel "held that the MDA preempted plaintiffs' loss of consortium claim 'to the extent that it was derivative of the pre-empted claims,'" 128 S. Ct. at 1006, a cursory reading of the case and of the specific page cited by Boston Scientific reveals that the Supreme Court was simply restating the conclusion reached by the district court.[6] This recitation of factual history of the case does not equate to a holding by the Supreme Court. However, Boston Scientific did accurately state that under Louisiana law, "a loss of consortium action is a derivative claim of the primary victim's injuries." Ferrell v. Fireman's Fund Ins. Co., 696 So. 2d 569, 575 (La. 1974). As this claim is derivative of the primary claims and all of McQuiston's

[6]In addition, the court notes that many of the quotes cited by Boston Scientific regarding Riegel are in reference to the district court opinion and many of the page citations are inaccurate.

primary claims have been dismissed, this claim must be dismissed as well.

III. CONCLUSION

Based on the foregoing, both Mr. and Mrs. McQuiston's claims against Boston Scientific are preempted by the MDA or derivative of such claims. Accordingly, Boston Scientific's motion for summary judgment is **GRANTED** and all claims made by Mr. and Mrs. McQuiston against Boston Scientific are **DISMISSED WITH PREJUDICE**.

A judgment consistent with the terms of this Memorandum Ruling shall issue herewith.

THUS DATED AND SIGNED at Shreveport, Louisiana, this 19th day of November, 2009.

JUDGE TOM STAGG